

REMARKS

Entry of the foregoing and reconsideration of the application identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.116 and in light of the remarks which follow, are respectfully requested.

At the outset, Applicants thank Examiner Kishore of the U.S. Patent and Trademark Office for his time and consideration in discussing the present application with Applicants' representative on October 19, 2007.

By the above amendments, claims 23-42 have been canceled without prejudice or disclaimer. New claims 43-69 have been added as set forth above. Support for the newly added claims can be found at least at the following portions of the present specification:

claims 43 and 60: page 8, line 23 to page 9, line 8, taken in connection with page 6, lines 6-13 and 31-32; page 11, line 29 to page 12, line 5; page 12, lines 16-19; and page 18, line 28 to page 19, line 6;

claims 44 and 45: page 9, lines 17-24, taken in connection with page 8, lines 5-7;

claims 46 and 47: page 14, lines 9-19;

claim 48: page 9, lines 26-31, taken in connection with page 11, lines 9-22;

claim 49: page 11, lines 9-28;

claim 50: page 9, lines 26-31;

claim 51: page 13, lines 9-28;

claim 52: page 12, line 30 to page 13, line 8;

claims 53 and 54: page 10, lines 1-4;

claim 55: page 12, lines 28-29;

claims 56-58: page 14, line 21 to page 15, line 2;

claim 59: page 7, lines 19-21;

claim 61: page 6, lines 16-21;

claim 62: page 11, lines 8-28;
claims 63 and 67: page 7, lines 2-5;
claim 64: page 9, lines 4-6;
claim 65, 66 and 68: page 6, lines 11-13 and 31-32; and
claim 69: page 7, lines 2-5.

In the Official Action, claims 23-30, 32-37 and 40-42 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,616,334 (*Janoff et al*). Claims 23-34, 36, 37 and 40-42 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,383,513 (*Watts et al*). Claims 24, 27-29, 35, 38 and 39 stand rejected under 35 U.S.C. §103(a) as being obvious over *Watts et al*. Claims 23-42 stand rejected under 35 U.S.C. §103(a) as being obvious over *Watts et al* in view of U.S. Patent No. 5,583,052 (*Portnoff et al*). Claims 23-42 stand rejected under 35 U.S.C. §103(a) as being obvious over *Janoff et al* in view of *Portnoff et al*. Claims 31 and 37 stand rejected under 35 U.S.C. §103(a) as being obvious over *Janoff et al* in combination with U.S. Patent No. 5,004,511 (*Leigh*). Without addressing the propriety of the above rejections, it is noted that such rejections are moot in light of the above cancellation of claims 23-42.

It is respectfully submitted that newly added claims 43-69 are not anticipated by or rendered obvious over the above applied documents. The applied documents fail to disclose or suggest a composition being optically clear and enabling visual inspection for presence of precipitates or an unassociated drug substance, as recited in independent claim 43. In addition, the applied documents do not disclose or suggest a method yielding a composition which is optically clear and free from precipitates or an unassociated drug substance, as recited in independent claim 60. There is simply no recognition or suggestion of an optically clear composition as is presently claimed.

As discussed in the instant specification at page 11, according to an exemplary aspect, the optical clarity of the composition can enable the claimed composition to be visually inspected prior to administration, for example, to observe whether such composition contains any precipitates or unassociated drug substance and to determine whether the composition is suitable for use. The applied documents have no recognition or suggestion of such advantage of the optical clarity of the composition, let alone that the disclosed compositions are in fact optically clear.

Accordingly, for at least the above reasons, it is apparent that the applied documents neither anticipate nor render obvious the claims of the present application.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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